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Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,034,267 was filed on September 22, 2004, under 35 U.S.C. § 156.

The assistance of your Office is requested in determining whether the product identified in the application, METVIXIA™ (methyl aminolevulinate hydrochloride),[1] has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use, and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156. According to the statute:

> (a) The term of a patent which claims a product, a method of using a product, or a method of manufacturing a product shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment granted under section 154(b) if —
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> . . .
>
> (5)(A) except as provided in subparagraph (B) or (C), the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of

[1]Although the proprietary name of the product was not provided in the application for patent term extension, it appears based on a review of publicly available information on FDA's web site that METVIXIA™ is the product in question. Applicant's representative should advise the PTO and the FDA if this is not correct.

the product under the provision of law under which such regulatory review period occurred;

. . . .

(f) For purposes of this section:

(1) The term "product" means:

(A) A drug product.

. . .

(2) The term "drug product" means the active ingredient of—

(A) a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act)

. . .

including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

35 U.S.C. § 156. Since methyl aminolevulinate hydrochloride is an ester of aminolevulinic acid hydrochloride, both fall within the scope of the same "product" as that term is defined by statute. Aminolevulinic acid hydrochloride had been previously approved by the FDA; see 68 Fed. Reg. 15730. Therefore, the approval for methyl aminolevulinate hydrochloride referenced in the application for patent term extension does not represent approval for "the first permitted commercial marketing or use of the product" as required by § 156(a)(5)(A), and U.S. Patent No. 6,034,267 is ineligible for extension.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7754 (telephone) or (571) 273-7754 (facsimile).

Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Donna M. Praiss
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